IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

DALE BURNINGHAM and LANA BURNINGHAM, Plaintiffs, v. WRIGHT MEDICAL GROUP, INC., WRIGHT MEDICAL TECHNOLOGY, INC., HARLAN C. AMSTUTZ, M.D., a California corporation, and HARLAN C. AMSTUTZ, M.D., an individual, Defendants.	**ORDER CERTIFYING QUESTIONS TO THE UTAH SUPREME COURT** Case No. 2:17-CV-92 District Judge Jill N. Parrish

Pursuant to Rule 41 of the Utah Rules of Appellate Procedure, the United States District Court for the District of Utah requests that the Utah Supreme Court answer the following questions of law:

1. Under Utah law, does the unavoidably unsafe exception to strict products liability in design defect claims recognized in Comment k to Section 402A of the Restatement (Second) of Torts apply to implanted medical devices?

2. If the answer to Question 1 is in the affirmative, does the exception apply categorically to all implanted medical devices, or does the exception apply only to some devices on a case-by-case basis?

3. If the exception applies on a case-by-case basis, what is the proper analysis to determine whether the exception applies?

4. If the answer to Question 1 is in the affirmative, does the exception require a showing that such devices were cleared for market through the FDA's premarket approval process as opposed to the § 510(k) clearance process?

These issues are controlling in this matter and "there appears to be no controlling Utah law." Utah R. App. P. 41(c)(1). The court acknowledges that the Utah Supreme Court may reformulate these questions. *See In re W. Side Prop. Assocs.*, 13 P.3d 168, 170–71 (Utah 2000).

I. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs Dale and Lana Burningham brought suit alleging that Mr. Burningham sustained injuries from implanted hip devices designed, manufactured, marketed, and sold by Defendants. The complaint alleges three causes of action involving the failure of three Class III medical devices, all of which were cleared by the Food and Drug Administration (FDA) pursuant to the Section 510(k) premarket notification process: (1) a Profemur Modular Neck implanted in Mr. Burningham's left hip, fractured on February 3, 2012 and revised on February 6, 2012; (2) a metal-on-metal failure of Conserve Components implanted in Mr. Burningham's right hip, revised on February 6, 2012; and (3) a metal-on-metal failure of Conserve Components implanted in Mr. Burningham's left hip, revised on March 27, 2013. Each of Plaintiffs' three causes of action alleges design defect claims arising under a theory of strict liability.

On April 24, 2017, Defendants filed a motion to dismiss, in which they argued, among other things, that the court should dismiss Plaintiffs' claims for strict liability design defect. Regarding the design defect claims, Defendants argued that the Profemur Modular Neck and the Conserve Components implanted in Mr. Burningham's hips are "unavoidably unsafe" products and are therefore categorically barred from strict liability design defect claims under the relevant exception to strict products liability set forth in Comment k to section 402A of the Restatement (Second) of Torts.

Comment k recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." But despite their dangerous nature, they are tremendously beneficial and should not be held to a

strict liability standard. Comment k gives the example of the rabies vaccine, which can lead to "very serious and damaging consequences when it is injected." But untreated rabies "invariably leads to a dreadful death," so "the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve." Restatement (Second) of Torts § 402A cmt. k (Am. Law Inst. 1965).

The Utah Supreme Court addressed the Comment k exception in *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991). There, the court "characterize[ed] all FDA-approved prescription medications as 'unavoidably safe,' . . . [thereby] expanding the literal interpretation of comment k." *Id.* at 90. Specifically, the court held that "a drug approved by the [FDA], properly prepared, compounded, packaged, and distributed, cannot as a matter of law be 'defective' in the absence of proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval." *Id.*

In their motion to dismiss, Defendants argued that the doctrine regarding unavoidably unsafe products "applies equally to medical devices like the Profemur Modular Neck and Conserve Components at issue." But Defendants did not cite any Utah authority suggesting that Utah applies the unavoidably unsafe doctrine in any context other than FDA-approved prescription drugs. Plaintiffs objected that Utah courts had never applied the unavoidably unsafe doctrine of Comment k to implanted medical devices and argued that Utah law clearly limited that doctrine's application to FDA-approved drugs.

After reviewing the relevant memoranda, the court noted that whether Comment k's unavoidably unsafe exception should apply to implanted medical devices appeared to be an issue of first impression in Utah. Consequently, on September 27, 2017, the court notified the parties that it was considering certifying the question to the Utah Supreme Court and requested

additional briefing. Both parties strongly opposed certification, but neither party cited Utah law that resolved the question. Instead, Plaintiffs insisted that, because no Utah court *had* applied the doctrine to medical devices, no Utah court *would* do so in the future. On the other hand, Defendants argued that the Utah Supreme Court's decision in *Grundberg* answered the question, even though neither *Grundberg* nor Comment k mentions medical devices, and despite *Grundberg*'s clear holding that "a broad grant of immunity from strict liability claims based on design defects should be extended to *FDA-approved prescription drugs* in Utah." *Grundberg*, 813 P.2d at 99 (emphasis added).

Consequently, over the parties' objections, the court determined to certify the issue to the Utah Supreme Court. In a January 22, 2018 order, the court ordered the parties to meet, confer, and submit a proposed statement of facts and proposed questions for certification.[1] It appears that the parties met. But rather than attempt to develop a stipulated statement of facts and questions in accordance with the court's order, the parties simply agreed to file their own proposed statements of facts and questions. Predictably, the parties' statements of facts are overlong, steeped in bias, and bear very little resemblance to each other. The parties' competing proposed questions are also vastly divergent. For this reason, the court drafted its own statement of facts and its own questions for certification.

II. LEGAL BACKGROUND

A certification order must state (1) the question of law to be answered, (2) that the question certified is a controlling issue of law in a proceeding before the certifying court, and (3) that there appears to be no controlling Utah law. Utah R. App. P. 41(c)(1). The court has stated

[1] In that order, the court also granted Defendants' motion in part and dismissed Plaintiffs' claims for breach of express warranty and negligent misrepresentation.

the questions of law to be answered above. Those questions represent controlling issues of law in this case. And there appears to be no controlling Utah law.

Rule 41 also provides that "the certifying court may also include in the order any additional reasons for its entry of the certification order." Utah R. App. P. 41(c)(3). Here, certification is also appropriate because resolution of these questions will have a significant impact on the bounds of strict liability for design defect claims brought under Utah law and because this issue has now come before federal courts twice in as many years. *See In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig.*, 178 F. Supp. 3d 1321, 1358 (N.D. Ga. 2016) (noting that "the law on Comment k in Utah [is] not fully mature"), *aff'd in part sub nom. Christiansen v. Wright Med. Tech., Inc.*, 851 F.3d 1203 (11th Cir. 2017).

Rule 41 does not require the certification order to provide background information beyond the facts and procedural history of the underlying action. But for the sake of convenience, the court includes three brief background notes regarding Comment k's application to medical devices, the distinction between a categorical and case-by-case application, and the FDA's premarket approval process.

A. COMMENT K AND MEDICAL DEVICES

In 1991, Utah adopted the unavoidably unsafe doctrine articulated in Comment k as a categorical bar to strict liability design defect claims against manufacturers of FDA-approved prescription drugs. *See Grundberg*, 813 P.2d at 99. But the Utah Supreme Court has not addressed whether that bar extends to medical devices.

While Utah has yet to decide this issue, other jurisdictions have extended the unavoidably unsafe doctrine beyond prescription drugs in more recent years. *See, e.g., Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Okla. 1994) (holding that "Comment k can apply to medical devices, particularly those which are implanted"); *Payne v. Paugh*, 360 P.3d 39, 50 (Wash Ct. App. 2015)

(holding that Comment k "applies to medical devices that have a high risk of possible harmful effects but are 'necessary regardless of the risks involved to the user'"); *Breen v. Synthes-Stratec, Inc.*, 947 A.2d 383, 388 (Conn. App. Ct. 2008) (concluding that Comment k "is applicable to medical devices such as the plates implanted in the plaintiff's body"); *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 384 (Cal. Ct. App. 1992) (adopting the Comment k standard for medical devices because "[a]s with prescription drugs, the harsher rule of strict liability may discourage manufacturers from researching and marketing new medical devices due to realistic fear of substantial adverse judgments, the high cost of strict liability insurance and the uncertainty that such insurance will even be available"). But some courts have refused to extend the doctrine to medical devices. *See, e.g.*, *Jenkins v. Boston Sci. Corp.*, No. 2:13-cv-09968, 2016 WL 1448867, at *5 (S.D.W. Va. Apr. 12, 2016) (rejecting the argument that Texas's categorical bar on strict liability design defect claims against FDA-approved prescription drugs would extend to a transvaginal surgical mesh).

B. CATEGORICAL AND CASE-BY-CASE APPLICATION

In *Grundberg*, the Utah Supreme Court adopted a broad, categorical application of Comment k to all FDA-approved prescription drugs. 813 P.2d at 99. But "courts are split on whether Comment k applies categorically to all prescription drugs or whether Comment k should only be applied as an affirmative defense on a case-by-case basis. The majority of courts take the latter approach . . . ." *Moss v. Wyeth Inc.*, 872 F. Supp. 2d 162, 167 (D. Conn. 2012) (listing cases taking the majority and minority positions).[2]

Courts are similarly split over the application of Comment k to medical devices. For example, Oklahoma applies Comment k to medical devices on a case-by-case basis. *See Tansy*,

[2] Justices Howe and Stewart dissented from the *Grundberg* majority largely because they would have applied a case-by-case approach rather than a categorical approach to immunity from strict liability.

890 P.2d at 886. However, California drew "a bright line within which the Comment k test is applied to all implanted medical devices." *Hufft*, 5 Cal. Rptr. 2d at 384.[3]

C. PREMARKET APPROVAL AND § 510(K) CLEARANCE

In *Grundberg*, the Utah Supreme Court placed particular emphasis on the role of FDA regulation. And the court made its broad grant of immunity from strict liability claims based on design defects "[i]n light of . . . the extensive regulatory system of the FDA." *Grundberg*, 813 P.2d at 99. But FDA regulation of prescription drugs and medical devices is different.

In 1976, Congress enacted the Medical Device Amendments of 1976 ("MDA"), amending the Federal Food, Drug, and Cosmetic Act of 1938. The MDA "classifies medical devices in three categories based on the risk that they pose to the public." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). Class III devices (like those implanted in Mr. Burningham) either "present[] a potential unreasonable risk of illness or injury," or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C).

To introduce a Class III device to the market, a manufacturer "must provide the FDA with a 'reasonable assurance' that the device is both safe and effective." *Medtronic*, 518 U.S. at 477 (citing § 360e(d)(2)). But "establishing this 'reasonable assurance,' which is known as the 'premarket approval,' or 'PMA' process, is a rigorous one." *Id.* On average, manufacturers must spend "an average of 1,200 hours on each submission." *Id.*

In contrast, the § 510(k) process (named after the number of the section of the original MDA) permits manufacturers to market Class III devices without rigorous PMA review if the devices are "substantially equivalent" to pre-existing devices. *See* 21 U.S.C. § 360e(b)(1)(B).

[3] The court notes that some jurisdictions appear to distinguish between implanted and non-implanted medical devices. Here, all three devices were implanted in Mr. Burningham's hips, so the question it has certified only concerns implanted devices.

The § 510(k) process "is completed in an average of only 20 hours." *Medtronic*, 518 U.S. at 478–79. Here, Defendants' products were cleared for market by way of § 510(k) clearance.

III. ORDER

The court **ORDERS** that, pursuant to Rule 41 of the Utah Rules of Appellate Procedure, the questions articulated above are certified to the Utah Supreme Court. The court **ORDERS** that the Clerk of the court shall transmit a copy of this certification to the parties and shall submit to the Utah Supreme Court a certified copy of this order. Should the Utah Supreme Court determine that any portion of the record be filed with it, this court further **ORDERS** the Clerk to transmit the records requested.

Signed February 15, 2018

BY THE COURT

Jill N. Parrish
United States District Court Judge